General

Guideline Title

ACR Appropriateness Criteria® radiologic management of uterine leiomyomas.

Bibliographic Source(s)

Burke CT, Ray CE Jr, Lorenz JM, Darcy MD, Fidelman N, Hohenwalter EJ, Kinney TB, Kolbeck KJ, Kouri BE, Nair AV, Rochon PJ, Shaw H, Vatakencherry G, Expert Panel on Interventional Radiology. ACR Appropriateness CriteriaÂ® radiologic management of uterine leiomyomas. [online publication]. Reston (VA): American College of Radiology (ACR); 2012. 8 p. [62 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Burke CT, Funaki BS, Ray CE Jr, Kinney TB, Kostelic JK, Loesberg A, Lorenz JM, Millward SF, Nemcek AA Jr, Owens CA, Shaw H, Silberzweig JE, Vatakencherry G, Expert Panel on Interventional Radiology. ACR Appropriateness Criteria® treatment of uterine leiomyomas. [online publication]. Reston (VA): American College of Radiology (ACR); 2009. 8 p.

Recommendations

Major Recommendations

ACR Appropriateness Criteria®

Clinical Condition: Radiologic Management of Uterine Leiomyomas

Variant 1: 45-year-old woman with multiple uterine fibroids resulting in a 20-week-sized uterus on physical examination and menorrhagia. The patient has a recent negative serum pregnancy test and has no desire for future fertility.

Treatment/Procedure	Rating	Comments
Hormonal therapy	3	May be useful as a temporizing therapy in some instances.
Magnetic resonance (MR)-guided high-frequency focused ultrasound ablation	2	
Endometrial ablation	2	Controls bleeding, but patient remains at risk for bulk-related symptoms eventually.
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Laparoscopic uterine artery occlusion	Rating	No long-term data. Unproven long-term clinical success.
Myomectomy	3	
Hysterectomy	8	Based on patient preference.
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 2: 29-year-old woman with multiple submucosal and intramural fibroids presents with menorrhagia and pelvic pain. Most of the fibroids measure <4 cm, with two dominant fibroids measuring >6 cm. The patient states that she does not desire future pregnancies and is concerned about the loss of femininity with hysterectomy.

Treatment/Procedure	Rating	Comments
Hormonal therapy	3	May be useful as a temporizing therapy in some instances.
MR-guided high-frequency focused ultrasound ablation	3	
Endometrial ablation	2	Useful for menorrhagia but not pelvic pain. Young patient may change her mind about pregnancy.
Uterine artery embolization	8	
Laparoscopic uterine artery occlusion	1	No long-term data. Unproven long-term clinical success.
Myomectomy	3	Suboptimal procedure due to multifocal fibroids.
Hysterectomy	4	Should be considered. Patient preference important.
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 3: 36-year-old woman with menometrorrhagia. On magnetic resonance imaging (MRI), she has three dominant leiomyomas, ranging in size from 6 to 8 cm and intramural in location. She states that she does not have plans for future pregnancy but would like to have the option in the future.

Treatment/Procedure	Rating	Comments
Hormonal therapy	3	May be useful as a temporizing therapy in some instances.
MR-guided high-frequency focused ultrasound ablation	4	Early data favorable, but long-term data lacking.
Endometrial ablation	1	
Uterine artery embolization	7	
Laparoscopic uterine artery occlusion	1	No long-term data. Unproven long-term clinical success.
Myomectomy	7	May be most viable option if lesions are anatomically amenable to myomectomy. Viable solution to preserve fertility.
Hysterectomy	2	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 4: 41-year-old woman with menorrhagia. MRI reveals a single 3 cm intramural fibroid and diffuse adenomyosis.

Treatment/Procedure	Rating	Comments
Hormonal therapy	3	May be useful as a temporizing therapy in some instances.
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Treatment/Procedure	Rating	Comments
MR-guided high-frequency focused ultrasound ablation	3	
Endometrial ablation	4	
Uterine artery embolization	7	Higher recurrence risk with adenomyosis.
Laparoscopic uterine artery occlusion	1	No long-term data. Unproven long-term clinical success.
Myomectomy	3	
Hysterectomy	7	May be best option, depending on patient preference.
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 5: 45-year-old woman with pelvic discomfort and 8 cm pedunculated subserosal fibroid on MRI.

Treatment/Procedure	Rating	Comments
Hormonal therapy	4	
MR-guided high-frequency focused ultrasound ablation	3	
Endometrial ablation	1	
Uterine artery embolization	7	
Laparoscopic uterine artery occlusion	2	
Myomectomy	8	
Hysterectomy	7	Depends on desire for future fertility.
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Variant 6: 43-year-old woman with constipation. MRI reveals a 12 cm subserosal leiomyoma compressing the rectum.

Treatment/Procedure	Rating	Comments
Hormonal therapy	3	May be useful as a temporizing therapy in some instances.
MR-guided high-frequency focused ultrasound ablation	3	
Endometrial ablation	1	
Uterine artery embolization	7	Less effective for bulk-related symptoms. If not an operative candidate or refuses surgery.
Laparoscopic uterine artery occlusion	1	No long-term data. Unproven long-term clinical success.
Myomectomy	8	May be most viable option if lesions are anatomically amenable to myomectomy.
Hysterectomy	7	
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate		

Summary of Literature Review

Introduction/Background

Uterine leiomyomas (also known as fibroids or myomas) are the most common tumor in women of reproductive age, affecting more than 66% of women by 50 years of age. They are the leading cause for hysterectomy in the United States. Leiomyoma treatment is typically indicated to treat

the symptoms of the fibroids, such as abnormal uterine bleeding, bulk-related symptoms, and/or pain.

Uterine Artery Embolization

Appropriate patient selection and management are integral to successful outcomes with uterine artery embolization (UAE). The following is a brief description of the procedure and patient management as detailed by the Society of Interventional Radiology Task Force on Uterine Artery Embolization.

Prior to UAE, all prospective patients should undergo a full gynecologic workup. Cross-sectional imaging, preferably ultrasound (US) or magnetic resonance imaging (MRI) is done to confirm the diagnosis of uterine leiomyomas and exclude other pelvic pathology. Viable pregnancy and active infection are two absolute contraindications for the procedure and must be excluded. The procedure is typically performed under conscious sedation using either a unilateral or bilateral common femoral artery approach, depending on operator preference. Both uterine arteries are selectively catheterized, when possible, with the catheter advanced distal to nontarget branches. Both uterine arteries are then embolized. The goal is the occlusion of all distal uterine artery branches feeding the leiomyomas(s). Particulate embolic agents are typically used to achieve a distal embolization. Afterward, the patient is observed and treated for postprocedure pain and/or nausea. The patient is followed closely for the first 24 to 48 hours after discharge for adequacy of pain and nausea control and to assess for potential complications. At 3 to 6 months following the procedure, the patient is re-evaluated for treatment efficacy. Follow-up imaging may also be performed to determine fibroid volume reduction and to assess for incomplete fibroid infarction.

Outcomes

UAE was first reported in 1995, and since that time numerous reports have been published documenting clinical success rates of 81%-100%. Currently, registries remain the largest source of data for evaluating the efficacy of UAE. Results from the Ontario Uterine Fibroid Embolization Trial, a multicenter, prospective registry, showed median uterine and dominant fibroid volume reductions of 35% and 42%, respectively. In addition, there was significant improvement for patients with menorrhagia (83%), dysmenorrhea (77%), and urinary frequency (86%) at 3 months after the procedure. One of the largest registries to date, the Fibroid Registry for Outcomes Data (FIBROID), comprised more than 3,000 women who underwent UAE at 72 sites. At 12 months, 95% of patients who were followed up reported symptomatic improvement and improved quality-of-life scores. Recently, 36-month data were published for more than 1,200 patients enrolled in this registry. These data showed continued statistically significant improvement in symptoms and quality of life based on questionnaires. During the 3-year period, 14.4% of the patients underwent additional procedures (9.8% repeat UAE, 2.8% myomectomy, and 1.8% hysterectomy).

Complications

Overall, the reported complication rates for UAE remain low, with major complications occurring in less than 3% of patients. More commonly, up to 10% of patients may need to be readmitted for pain control. Amenorrhea can occur in up to 10% of patients following UAE. The risk of permanent amenorrhea appears to be age-dependent. For women younger than age 45 the risk is less than 2% to 3%, whereas for women older than age 45 it is up to 20%.

Durability

As with other uterine sparing procedures, there is uncertainty about the durability of symptom relief with UAE. Trying to identify prospectively which patients will have better clinical results is difficult. Within the registry data, the two groups that showed better long-term outcomes were women presenting with abnormal uterine bleeding and women with smaller leiomyomas. Nevertheless, in a small retrospective analysis, researchers reported symptomatic improvement at 16 months in five of six patients with diffuse leiomyomatosis. In addition, a recent retrospective study showed no difference in outcomes or complications in patients with large fibroid volumes when compared with published outcomes for other patients treated with UAE. Another retrospective analysis found two preoperative factors to be predictive of success: hypervascularity of the nodules and multiplicity of nodules. Conversely, another study found no correlation between fibroid characteristics and outcome.

Overall, there is 20% to 25% incidence of symptom recurrence at 5 to 7 years after UAE, though most women report continued high quality-of-life scores. One study reported continued symptom relief in 67 of 93 women (72%) at a median follow-up of 54 months. Of those patients with treatment failure, 11 (42%) underwent a hysterectomy. In a separate study, 73% of patients maintained symptom control 5 years after the procedure. Despite the relatively high recurrence rate in long-term follow-up, repeat embolization has been shown to be effective for most of these patients, and UAE does not preclude other therapies when unsuccessful.

Other Treatment Options

Hysterectomy

Hysterectomy is the most common treatment for symptomatic fibroids; approximately 150,000 to 200,000 hysterectomies are performed each

year in the United States for fibroids, and it is considered the definitive therapy. The primary advantage is that by completely removing the uterus, there is little potential for fibroid recurrence. In addition, alternative causes of symptoms, such as adenomyosis, will also be effectively treated. Overall, this therapy is met with very high patient satisfaction scores, with up to 90% of patients reporting at least moderate satisfaction 2 years after hysterectomy for symptomatic fibroids. However, many women who undergo hysterectomy later regret the loss of fertility or have concerns regarding their femininity.

To date, there have been multiple prospective, randomized trials comparing UAE to hysterectomy. These studies have shown both treatments to have very high clinical success rates and very high rates of patient satisfaction. Within the study performed by the Randomized Trial of Embolization versus Surgical Treatment for Fibroids (REST) investigators, women with symptomatic fibroids were randomly assigned to undergo either UAE or surgery in a ratio of 2:1 and followed for 1 year. There were 95 women in the UAE group and 45 women in the surgical group, with most women in the surgical group undergoing hysterectomy. The UAE group had significantly shorter hospitalization stays and shorter recovery times before returning to work. At 12 months, the patients who underwent surgery had significantly better symptom scores, though there was no significant difference in quality-of-life scores.

The EMbolization versus hysterectoMY (EMMY) trial randomized 177 patients to undergo either UAE or hysterectomy. There was no significant difference in physical component summary scores beyond 6 weeks, and more than 90% of patients in each group were at least moderately satisfied with their procedure at the 2-year follow-up. These improvements remained stable, with no significant difference between the two groups at 5-year follow-up.

As part of the EMMY trial, concerns over body image and sexuality were also evaluated between patients receiving hysterectomies and those receiving UAEs. At 2 years, there was no statistical difference in the sexuality or body image scores of the two groups.

In a multicenter, nonrandomized prospective study hysterectomy was compared to myomectomy and embolization for improving uterine fibroid-related symptoms and the effect on health-related quality of life. This study, despite showing all three therapies as extremely effective in reducing fibroid-related symptoms, did demonstrate a significantly better health-related quality-of-life advantage for patients treated with hysterectomy.

Myomectomy

Myomectomy is a surgical alternative that may be performed when uterine conservation is desired. As with other uterine-sparing procedures, there is a risk for myoma recurrence. Using either an abdominal or laparoscopic approach, the recurrence rate ranges from 23% to 33%. In a large, multicenter study, laparoscopic myomectomy was associated with 2% major complication and 9% minor complication rates.

At least three studies have been performed directly comparing myomectomy to UAE. In one study, there was a reduction in the procedural and recovery times, as well as fewer adverse events, with UAE; similar rates of clinical success were reported. Another study reported significantly higher symptomatic improvement scores for patients undergoing UAE compared with myomectomy, but there was no significant difference in patient satisfaction scores. A prospective, nonrandomized comparison study demonstrated that UAE performed with spherical polyvinyl alcohol (PVA) had a significantly greater sustained reduction in tumor-related symptoms up to 24 months after intervention, with fewer complications, compared to myomectomy.

High-Intensity Focused Ultrasound

MR-guided high-intensity focused ultrasound (HIFU or MRgFUS) is another uterine-sparing option to treat focal leiomyomas. It is noninvasive, though each treatment may take several hours to complete. Its use currently is restricted to patients with fewer than six leiomyomas or leiomyoma volume less than 900 cm^3.

To date, there is little long-term information on the efficacy of this technology. It has been reported that myomas treated with HIFU have nearly 50% volume reduction at 1 year, but viable cells are present at biopsy in nearly 26% of specimens. A group of researchers report a 24-month volume reduction of 40% with significant symptomatic improvement at 6 months that remained stable at 24-month follow-up. One multicenter trial demonstrated significant reduction in fibroid-related symptoms in 70% of patients at 6 months and 51% of patients at 12 months.

Endometrial Ablation (EA)

EA is used for treating abnormal uterine bleeding from a variety of causes, including symptomatic submucosal myomas. Because it ablates the uterine cavity, it should not be used in women desiring future pregnancy. There are also uterine cavity size limitations for most currently available devices, with most devices able to treat uterine cavities up to 10 cm in size. In a study of 438 women treated with EA for menorrhagia, there was >95% overall patient satisfaction. Within this cohort, 143 patients were diagnosed preoperatively for uterine fibroids, two of which went on to hysterectomy due to persistent symptoms associated with the uterine fibroids. A separate study found a 23% failure rate in treating patients with submucosal fibroids compared with a failure rate of 4% in patients with normal uterine cavities.

Laparoscopic Uterine Artery Occlusion (LUAO)

There are limited published data about LUAO as a stand-alone treatment for uterine leiomyomas. In a small retrospective study, 9% of women treated with LUAO developed myoma recurrence at a median follow-up of 23.6 months. There are several studies comparing LUAO to UAE. A randomized evaluation of 20 patients found similar outcomes between the two procedures for menstrual blood loss, uterine volume, and volume of the dominant fibroid at 6 months, though menorrhagia symptoms did recur in 4 out of 10 patients in the LUAO group. In another small randomized controlled trial, LUAO achieved shorter hospital stays and reduced procedural pain compared to UAE, while achieving similar 3-month clinical success rates. In a separate study, the degree of bleeding reduction was similar between the two procedures. In this study, only 4% of patients treated with UAE continued to complain of symptoms, compared with 21% in the LUAO group (though this finding did not reach statistical significance). At a median follow-up of 48 months, there was clinical failure and symptom recurrence in 48% of patients treated with LUAO compared with 17% of patients treated with UAE. In a prospective randomized study that included 96 patients, there was no significant difference in outcomes between the two treatment groups at 12 months.

Pharmaceutical Treatment

The least invasive treatment option remains medical therapy with either oral contraceptive medication or gonadotropin-releasing hormone (GnRH) agonists/antagonists. Oral contraceptives may manage bleeding symptoms effectively, especially in women with small fibroids. GnRH agonists have been shown in several studies not only to be effective against symptoms of bleeding, but also to result in reduction in uterine volume and myoma volume, making them effective against bulk-related symptoms. However, these agents have several drawbacks. First, once the agent is discontinued, the fibroids quickly return to their previous volume and the fibroid-related symptoms typically recur. In addition, chronic use of GnRH agonists results in trabecular bone loss. Therefore, these agents are typically used for temporary situations, such as to reduce uterine and myoma size prior to surgical therapy.

Other Considerations

Fertility

The issue of fertility following UAE remains an area of great controversy. The impact on future fertility and subsequent delivery remains uncertain. It has been shown that over 60% of women who attempted to become pregnant after UAE had abnormal hysteroscopies. However, the significance of these findings remains unknown. There are reports of uncomplicated pregnancies following UAE, but because of small sample sizes, the overall risk remains unclear. In one study, 33 out of 56 women who went on to get pregnant following UAE had successful outcomes. However, this and other studies have shown an increased incidence of delivery by cesarean section in the UAE patient population.

There have been several reports comparing the impact of UAE and myomectomy on fertility. One multicenter retrospective trial found that women treated with fibroid embolization were at an increased risk for preterm delivery and breech presentation when compared with women treated with myomectomy. In this same study, there was also an increased risk of postpartum hemorrhage and spontaneous abortion in the UAE group, but this difference did not reach statistical significance. Furthermore, in a prospective, randomized comparison, there was a statistically significant advantage for myomectomy in both the number of successful pregnancies and the number of early pregnancy losses. When the risk of future pregnancy complications was studied in patients undergoing either UAE or LUAO, there was also an increased risk of spontaneous abortion following UAE compared with LUAO.

Another treatment option for patients who are candidates is MRgFUS. However, to date, there is little information regarding the issue of fertility following MRgFUS. In a review of registry data, 54 pregnancies were reported in 51 women. Of these, 41% resulted in live births and 28% in spontaneous abortions. Of those who delivered, there was a 93% term delivery rate with only one preterm birth (36 weeks). Forty-three percent of pregnancies had an associated complication, but no pattern of complications was seen.

Adenomyosis

Adenomyosis may be a cause of abnormal uterine bleeding with or without the presence of fibroids. UAE has shown early success in controlling the symptoms of bleeding with adenomyosis. The long-term durability of this success is questionable, with recurrence rates at 2 years of approximately 40% to 50%.

Cost-Effectiveness

Refer to the "Cost Analysis" field for information on cost effectiveness of UAE and hysterectomy.

Summary

- UAE is effective in managing symptomatic uterine fibroids.

- UAE is more cost-effective than hysterectomy in the short term, but hysterectomy becomes more cost-effective in the long term.
- UAE and myomectomy have similar clinical success and complication rates.
- Myomectomy may be superior to UAE in women planning future pregnancy.
- UAE is effective against symptoms related to adenomyosis; however, the success may be limited by high recurrence rates.

Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

Scope

Disease/Condition(s)

Uterine leiomyomas (also known as fibroids or myomas)

Guideline Category

Evaluation

Management

Treatment

Clinical Specialty

Obstetrics and Gynecology

Radiology

Surgery

Intended Users

Health Plans

Hospitals

Managed Care Organizations

Physicians

Utilization Management

Guideline Objective(s)

To evaluate the appropriateness of treatment procedures for patients with uterine leiomyomas

Target Population

Patients with uterine leiomyomas

Interventions and Practices Considered

1. Hormonal therapy
2. Magnetic resonance (MR)-guided high-frequency focused ultrasound ablation
3. Endometrial ablation
4. Uterine artery embolization (UAE)
5. Laparoscopic uterine artery occlusion
6. Myomectomy
7. Hysterectomy

Major Outcomes Considered

- Effectiveness of treatment interventions in the management of uterine leiomyomas in terms of fibroid volume reduction, symptomatic improvement, quality of life, and patient satisfaction
- Success rates and complication rates of procedures
- Cost-effectiveness of uterine artery embolization (UAE) and hysterectomy

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Procedure

The Medline literature search is based on keywords provided by the topic author. The two general classes of keywords are those related to the condition (e.g., ankle pain, fever) and those that describe the diagnostic or therapeutic intervention of interest (e.g., mammography, MRI).

The search terms and parameters are manipulated to produce the most relevant, current evidence to address the American College of Radiology Appropriateness Criteria (ACR AC) topic being reviewed or developed. Combining the clinical conditions and diagnostic modalities or therapeutic procedures narrows the search to be relevant to the topic. Exploding the term "diagnostic imaging" captures relevant results for diagnostic topics.

The following criteria/limits are used in the searches.

1. Articles that have abstracts available and are concerned with humans.
2. Restrict the search to the year prior to the last topic update or in some cases the author of the topic may specify which year range to use in the search. For new topics, the year range is restricted to the last 5 years unless the topic author provides other instructions.
3. May restrict the search to Adults only or Pediatrics only.
4. Articles consisting of only summaries or case reports are often excluded from final results.

The search strategy may be revised to improve the output as needed.

Number of Source Documents

The total number of source documents identified as the result of the literature search is not known.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Strength of Evidence Key

Category 1 - The conclusions of the study are valid and strongly supported by study design, analysis and results.

Category 2 - The conclusions of the study are likely valid, but study design does not permit certainty.

Category 3 - The conclusions of the study may be valid but the evidence supporting the conclusions is inconclusive or equivocal.

Category 4 - The conclusions of the study may not be valid because the evidence may not be reliable given the study design or analysis.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The topic author drafts or revises the narrative text summarizing the evidence found in the literature. American College of Radiology (ACR) staff draft an evidence table based on the analysis of the selected literature. These tables rate the strength of the evidence for all articles included in the narrative text.

The expert panel reviews the narrative text, evidence table, and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the table. Each individual panel member forms his/her own opinion based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Modified Delphi Technique

The appropriateness ratings for each of the procedures included in the Appropriateness Criteria topics are determined using a modified Delphi methodology. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. American College of Radiology (ACR) staff distributes surveys to the panelists along with the evidence table and narrative. Each panelist interprets the available evidence and rates each procedure. The surveys are completed by panelists without consulting other panelists. The ratings are a scale between 1 and 9, which is further divided into three categories: 1, 2, or 3 is defined as "usually not appropriate"; 4, 5, or 6 is defined as "may be appropriate"; and 7, 8, or 9 is defined as "usually appropriate." Each panel member assigns one rating for each procedure per survey round. The surveys are collected and the results are tabulated, de-identified and redistributed after each round. A maximum of three rounds are conducted. The modified Delphi technique enables each panelist to express individual interpretations of the evidence and his or her expert opinion without excessive bias from fellow panelists in a simple, standardized and economical process.

Consensus among the panel members must be achieved to determine the final rating for each procedure. Consensus is defined as eighty percent (80%) agreement within a rating category. The final rating is determined by the median of all the ratings once consensus has been reached. Up to three rating rounds are conducted to achieve consensus.

If consensus is not reached, the panel is convened by conference call. The strengths and weaknesses of each imaging procedure that has not reached consensus are discussed and a final rating is proposed. If the panelists on the call agree, the rating is accepted as the panel's consensus. The document is circulated to all the panelists to make the final determination. If consensus cannot be reached on the call or when the document is

circulated, "No consensus" appears in the rating column and the reasons for this decision are added to the comment sections.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Cost-Effectiveness

There have been several studies comparing the cost-effectiveness of uterine artery embolization (UAE) and hysterectomy. Two studies out of Europe favored UAE as a more cost-effective treatment. The investigators of the EMbolization versus hysterectoMY (EMMY) trial showed a 37% cost savings with UAE at 24 months after treatment. The savings were seen in both the direct medical costs and the indirect costs from lost workdays. However, the medical cost advantage at 2 years was partially offset by additional procedures incurred by the UAE group due to symptom recurrence in the follow-up period.

A second investigation, the HOPEFUL study, used a probabilistic decision model to create a complex decision tree to compare the cost-effectiveness of the two procedures. In this study, UAE was also shown to be more cost-effective than hysterectomy up to 1 year after the procedure. Over time, however, UAE becomes more expensive than hysterectomy because of the cost of additional follow-up procedures. The authors concluded that "young women with less severe symptoms would benefit less from UAE than those who are older with more severe symptoms."

In a study using Markov modeling, UAE proved to be more cost-effective than either hysterectomy or myomectomy at 1 year. However, at 5 years, hysterectomy proved to be the least expensive option.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current literature and expert panel consensus.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Selection of appropriate procedures for the treatment of uterine leiomyomas

Potential Harms

- *Uterine Artery Embolization (UAE)*. Overall, the reported complication rates for UAE remain low, with major complications occurring in less than 3% of patients. More commonly, up to 10% of patients may need to be readmitted for pain control. Amenorrhea can occur in up

to 10% of patients following UAE. The risk of permanent amenorrhea appears to be age-dependent. For women younger than age 45 the risk is less than 2% to 3%, whereas for women older than age 45 years it is up to 20%. The issue of fertility following UAE remains an area of great controversy. The impact on future fertility and subsequent delivery remains uncertain.

- *Hysterectomy*. Many women who undergo hysterectomy later regret the loss of fertility or have concerns regarding their femininity.
- *Myomectomy*. Using either an abdominal or laparoscopic approach, the recurrence rate ranges from 23% to 33%. In a large, multicenter study, laparoscopic myomectomy was associated with 2% major complication and 9% minor complication rates.
- *Pharmaceutical Treatment*. Medical therapy with either oral contraceptive medication or gonadotropin-releasing hormone (GnRH) agonists/antagonists has several drawbacks. First, once the agent is discontinued, the fibroids quickly return to their previous volume and the fibroid-related symptoms typically recur. In addition, chronic use of GnRH agonists results in trabecular bone loss. Therefore, these agents are typically used for temporary situations, such as to reduce uterine and myoma size prior to surgical therapy.

Contraindications

Contraindications

Viable pregnancy and active infection are two absolute contraindications for uterine artery embolization (UAE) and must be excluded.

Qualifying Statements

Qualifying Statements

The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Burke CT, Ray CE Jr, Lorenz JM, Darcy MD, Fidelman N, Hohenwalter EJ, Kinney TB, Kolbeck KJ, Kouri BE, Nair AV, Rochon PJ, Shaw H, Vatakencherry G, Expert Panel on Interventional Radiology. ACR Appropriateness CriteriaÂ® radiologic management of uterine leiomyomas. [online publication]. Reston (VA): American College of Radiology (ACR); 2012. 8 p. [62 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2009 (revised 2012)

Guideline Developer(s)

American College of Radiology - Medical Specialty Society

Source(s) of Funding

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

Guideline Committee

Committee on Appropriateness Criteria, Expert Panel on Interventional Radiology

Composition of Group That Authored the Guideline

Panel Members: Charles T. Burke, MD (*Principal Author*); Charles E. Ray, Jr, MD, PhD (*Panel Chair*); Jonathan M. Lorenz, MD (*Panel Vice-Chair*); Michael D. Darcy, MD; Nicholas Fidelman, MD; Eric J. Hohenwalter, MD; Thomas B. Kinney, MD; Kenneth J. Kolbeck, MD; Brian E. Kouri, MD; Ajit V. Nair, MD; Paul J. Rochon, MD; Howard Shaw, MD; George Vatakencherry, MD

Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Burke CT, Funaki BS, Ray CE Jr, Kinney TB, Kostelic JK, Loesberg A, Lorenz JM, Millward SF,

Nemcek AA Jr, Owens CA, Shaw H, Silberzweig JE, Vatakencherry G, Expert Panel on Interventional Radiology. ACR Appropriateness Criteria® treatment of uterine leiomyomas. [online publication]. Reston (VA): American College of Radiology (ACR); 2009. 8 p.

Guideline Availability

Electronic copies: Available from the American College of Radiology (ACR) Web site .

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

Availability of Companion Documents

The following are available:

- ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site .
- ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 1 p. Electronic copies: Available in PDF from the ACR Web site .
- ACR Appropriateness Criteria®. Evidence table development – diagnostic studies. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available in PDF from the ACR Web site .
- ACR Appropriateness Criteria®. Evidence table development – therapeutic studies. Reston (VA): American College of Radiology; 2013 Nov. 4 p. Electronic copies: Available in PDF from the ACR Web site .
- ACR Appropriateness Criteria®. Procedure information. Reston (VA): American College of Radiology; 1 p. Electronic copies: Available in PDF from the ACR Web site .
- ACR Appropriateness Criteria® radiologic management of uterine leiomyomas. Evidence table. Reston (VA): American College of Radiology; 2012. 19 p. Electronic copies: Available from the ACR Web site .

Patient Resources

None available

NGC Status

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Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion-criteria.aspx.

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